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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

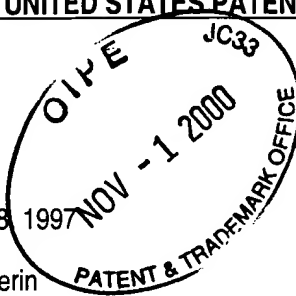
Applicant(s): Boyle et al.

Serial No.: 08/974,186

Filed: November 18, 1997

For: Osteoprotegerin

Docket No.: A-378D5C



Group Art Unit No.: 1632

Examiner: Campell, B.

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AMENDMENT AFTER FINAL REJECTION UNDER 37 CFR 1.116

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Office Action dated April 28, 2000 in which Claims 49-53 were rejected under 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the rejection is requested in view of the remarks set forth below.

REMARKS

Claims 49-53 are currently pending in the application and are directed to a method of regulating levels of osteoprotegerin (OPG) in an animal comprising modifying the animal with a gene encoding OPG.

Claims 49-53 stand rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not enable the claimed subject matter. The Examiner has relied on the argument that the claims are allegedly limited to a method of treatment using gene therapy and are alleged to lack enablement in view of the failure to bring nucleic acid based therapeutic drugs, particularly anti-sense and gene therapy drugs, to market.

Applicants maintain that the Examiner has not established a *prima facie* case of nonenablement. The burden falls on the Examiner to establish reasons as to why the specification does not enable the claimed invention. *In re Marzochi* 169 USPQ 367 (CCPA, 1971).

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

October 30, 2000

Date

Signature